Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Toxicology Data Management System

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Report Date: 06/05/2013

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER

Study Summary

Laboratory Name	Study Number	Study Start Date	Length of Study in Days	Number of Animals Total and (#/Cage)	Number Surviving and (Mean Life Span)	Maximum Mean Weekly Body Weight	Chemical
					Male		
Battelle Columbus Laboratory Battelle Columbus Laboratory	052000904 059601406	11/09/04 09/26/06	730 730	50(1) 50(1)	24(645) 25(660)	57.1 55.9	beta-Picoline Water disinfection byproducts (Bromodichloroacetic acid)
					Female		
Battelle Columbus Laboratory Battelle Columbus Laboratory	052000904 059601406	11/08/04 09/25/06	729 729	50(5) 50(5)	38(702) 30(680)	67.4 63.5	beta-Picoline Water disinfection byproducts (Bromodichloroacetic acid)

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

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Report Date: 06/05/2013

Contract/Lab: All Laboratories Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER

Length of Study: CHRONIC

Male **Female** #All Organs: **Benign Tumors** 36/50 (72%)43/50 (86%)40/50 (80%)36/50 (72%)**Overall Incidence** Total 79/100 (79%) Mean 79% SD 9.9% Total 76/100 (76%) Mean 76% SD 5.66% #All Organs: **Malignant Tumors** 36/50 (72%)30/50 (60%)29/50 (58%)31/50 (62%)**Overall Incidence** Total 66/100 (66%) Mean 66% SD 8.49% Total 60/100 (60%) Mean 60% SD 2.83% #All Organs: **Malignant and Benign Tumors** 48/50 (96%)48/50 (96%)43/50 (86%)45/50 (90%) Overall Incidence Total 96/100 (96%) Mean 96% SD 0% Total 88/100 (88%) Mean 88% SD 2.83% #All Organs: Hemangioma 1/50 (2%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 1/100 (1%) Mean 1% SD 1.41% Total 0/100 (0%) Mean 0% SD 0% **#All Organs:** Hemangiosarcoma 6/50 (12%)5/50 (10%)3/50 (6%)6/50 (12%) **Overall Incidence** Total 11/100 (11%) Mean 11% SD 1.41% Total 9/100 (9%) Mean 9% SD 4.24% **#All Organs:** Hemangiosarcoma or Hemangioma 7/50 (14%)5/50 (10%)3/50 (6%)6/50 (12%) **Overall Incidence** 12/100 (12%) Mean 12% SD 2.83% 9/100 (9%) Mean 9% SD 4.24% Total Total

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER Page: 184

			Male				Female	
#All Organs: Histiocytic Sarcoma								
		0/50 (0%)	1/50 (2%)			1/50 (2%)	2/50 (4%)	
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	3/100 (3%)	Mean 3%	SD 1.41%
#All Organs: Malignant Lymphoma: Hi	stiocytic, Lym	phocytic, Mixed, NOS, or	Undifferentiated Cel	I Туре				
		0/50 (0%)	0/50 (0%)			14/50 (28%)	6/50 (12%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	20/100 (20%)	Mean 20%	SD 11.31%
#All Organs: Mesothelioma: Benign								
		1/50 (2%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	0/100 (0%)	Mean 0%	SD 0%
#All Organs: Mesothelioma: Benign, N								
		1/50 (2%)	1/50 (2%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	2/100 (2%)	Mean 2%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#All Organs: Mesothelioma: Malignant								
		0/50 (0%)	1/50 (2%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	0/100 (0%)	Mean 0%	SD 0%
#All Organs: Osteoma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	1/50 (2%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	1/100 (1%)	Mean 1%	SD 1.41%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER **Page:** 185

			Male				Female	
#All Organs: Osteosarcoma		0/50 (00/)	0/50 /00/			0/50 (40/)	0/50 (00/)	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	2/50 (4%) 2/100 (2%)	0/50 (0%) Mean 2%	SD 2.83%
#All Organs: Osteosarcoma or Osteoma	1	0/50 (0%)	0/50 (0%)			2/50 (4%)	1/50 (2%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	3/100 (3%)	Mean 3%	SD 1.41%
*Adrenal Cortex: Adenoma		2/49 (4%)	2/50 (4%)			0/49 (0%)	0/49 (0%)	
Overall Incidence	Total	4/99 (4.04%)	Mean 4.04%	SD 0.06%	Total	0/98 (0%)	Mean 0%	SD 0%
*Adrenal Cortex: Plasma Cell Tumor Maligna	ant	0/49 (0%)	0/50 (0%)			0/49 (0%)	0/49 (0%)	
Overall Incidence	Total	0/99 (0%)	Mean 0%	SD 0%	Total	0/98 (0%)	Mean 0%	SD 0%
*Adrenal Medulla: Pheochromocytoma Benig	n	0/49 (0%)	0/50 (0%)			1/49 (2%)	0/50 (0%)	
Overall Incidence	Total	0/49 (0%)	Mean 0%	SD 0%	Total	1/99 (1.01%)	Mean 1.02%	SD 1.44%
*Adrenal Medulla: Pheochromocytoma Maligr	nant							•••••
Overall Incidence	Total	0/49 (0%) 0/99 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/49 (0%) 0/99 (0%)	0/50 (0%) Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER

Length of Study: CHRONIC

Contract/Lab: All Laboratories

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			Male				Female	
*Adrenal Medulla: Pheochromocytoma: Ben	nign, Complex,	Malignant, NOS 0/49 (0%)	0/50 (0%)			1/49 (2%)	0/50 (0%)	
Overall Incidence	Total	0/49 (0%)	Mean 0%	SD 0%	Total	1/99 (1.01%)	Mean 1.02%	SD 1.44%
#Blood Vessel: Hemangioma								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
*Bone Marrow: Hemangioma		0/50 /00/	0/50 (00)			0/40 (0%)	0/50 (00/)	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/49 (0%) 0/99 (0%)	0/50 (0%) Mean 0%	SD 0%
*Bone Marrow: Hemangiosarcoma		2/50 (4%)	0/50 (0%)			1/49 (2%)	0/50 (0%)	
Overall Incidence	Total	2/100 (2%)	Mean 2%	SD 2.83%	Total	1/99 (1.01%)	Mean 1.02%	SD 1.44%
*Bone Marrow: Mast Cell Tumor Malignal	nt							
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/49 (0%) 0/99 (0%)	0/50 (0%) Mean 0%	SD 0%
*Bone Marrow: Plasma Cell Tumor Malig	nant	0/50 (0%)	0/50 (0%)			0/49 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/49 (0%)	0/50 (0%) Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER Page: 187

			Male				Female	
*Bone Marrow: Sarcoma		0/50 (00/)	0/50 (00/)			0/40 (00/)	0/50 (00/)	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/49 (0%) 0/99 (0%)	0/50 (0%) Mean 0%	SD 0%
#Bone: Fibroma		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Bone: Hemangiosarcoma								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Bone: Osteoma								
Overall Incidence	Total	0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	1/100 (1%)	Mean 1%	SD 1.41%
#Bone: Osteosarcoma		•••••			•••••			
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	2/50 (4%) 2/100 (2%)	0/50 (0%) Mean 2%	SD 2.83%
#Bone: Osteosarcoma or Osteoma								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	2/50 (4%) 3/100 (3%)	1/50 (2%) Mean 3%	SD 1.41%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: MICE
Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER Page: 188

			Male				Female	
#Bone: Sarcoma		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	25.00
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
*Brain: Granular Cell Tumor Ber	nign	0/50 (0%)	0/50 (0%)			0/50 (0%)	0/49 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/99 (0%)	Mean 0%	SD 0%
*Brain: Meningioma Benign		0/20 (00)	(201)			2/22 (221)	(00)	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/99 (0%)	0/49 (0%) Mean 0%	SD 0%
*Brain: Meningioma Malignant		0/50 (0%)	1/50 (2%)			0/50 (0%)	0/49 (0%)	
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	0/99 (0%)	Mean 0%	SD 0%
*Brain: Meningioma: Benign, Ma	alignant, NOS	0/50 (0%)	1/50 (2%)			0/50 (0%)	0/49 (0%)	
Overall Incidence	Total	1/100 (1%)	1/50 (2%) Mean 1%	SD 1.41%	Total	0/99 (0%)	Mean 0%	SD 0%
*Brain: Oligodendroglioma Mali	gnant							
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/99 (0%)	0/49 (0%) Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER **Page:** 189

			Male				Female	
*Brain: Oligodendroglioma, Gliom	a, or Astrocy	/toma						
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/49 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/99 (0%)	Mean 0%	SD 0%
*Brain: Schwannoma Malignant								
		0/50 (0%)	0/50 (0%)	00.00/		0/50 (0%)	0/49 (0%)	00.00
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/99 (0%)	Mean 0%	SD 0%
*Clitoral/Preputial Gland: Hemangioma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/47 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/97 (0%)	Mean 0%	SD 0%
*Clitoral/Preputial Gland: Hemangiosarcoma		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/47 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/97 (0%)	Mean 0%	SD 0%
#Coagulating Gland: Granular Cell Tumor								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Coagulating Gland: Sarcoma		0/50 (00)	0/50 /00/			0/50 (00/)	0/50 (00)	
Occupation of days a	T-1-1	0/50 (0%)	0/50 (0%)	00.00/	T-1-1	0/50 (0%)	0/50 (0%)	OD 00/
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER **Page:** 190

			Male				Female	
#Esophagus: Squamous Cell Carcinoma	1							
•		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Eye: Melanoma Malignant								
		0/50 (0%)	1/50 (2%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	0/100 (0%)	Mean 0%	SD 0%
#Harderian Gland: Adenoma								
		5/50 (10%)	6/50 (12%)			2/50 (4%)	5/50 (10%)	
Overall Incidence	Total	11/100 (11%)	Mean 11%	SD 1.41%	Total	7/100 (7%)	Mean 7%	SD 4.24%
#Harderian Gland: Carcinoma								
	-	2/50 (4%)	0/50 (0%)	00.000/	-	2/50 (4%)	0/50 (0%)	00.000/
Overall Incidence	Total	2/100 (2%)	Mean 2%	SD 2.83%	Total	2/100 (2%)	Mean 2%	SD 2.83%
#Harderian Gland: Carcinoma or Adenoma								
		7/50 (14%)	6/50 (12%)			4/50 (8%)	5/50 (10%)	
Overall Incidence	Total	13/100 (13%)	Mean 13%	SD 1.41%	Total	9/100 (9%)	Mean 9%	SD 1.41%
*Heart: Hemangiosarcoma								
		1/50 (2%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	0/100 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Page: 191

Report Date: 06/05/2013

Route: ORAL Vehicle: WATER

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female** #Intestine Large: Cecum: Adenoma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/100 (0%) Mean 0% SD 0% Total 0/100 (0%) Mean 0% SD 0% #Intestine Large: Cecum: Carcinoma 0/50 (0%)1/50 (2%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 1/100 (1%) Mean 1% SD 1.41% Total 0/100 (0%) Mean 0% SD 0% #Intestine Large: Cecum: Carcinoma or Adenoma 0/50 (0%)1/50 (2%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 1/100 (1%) Mean 1% SD 1.41% Total 0/100 (0%) Mean 0% SD 0% #Intestine Large: Cecum: Leiomyoma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/100 (0%) Mean 0% SD 0% Total 0/100 (0%) Mean 0% SD 0% #Intestine Large: Cecum: Leiomyosarcoma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/100 (0%) Mean 0% SD 0% Total 0/100 (0%) Mean 0% SD 0% #Intestine Large: Colon/Rectum: Leiomyosarcoma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/100 (0%) Mean 0% SD 0% 0/100 (0%) Mean 0% SD 0% Total

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER Page: 192

			Male				Female	
#Intestine Small: Duodenum: Adenoma								
		0/50 (0%)	1/50 (2%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	0/100 (0%)	Mean 0%	SD 0%
#Intestine Small: Duodenum: Carcinoma								
		0/50 (0%)	1/50 (2%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	0/100 (0%)	Mean 0%	SD 0%
#Intestine Small: Duodenum: Leiomyosarcoma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Intestine Small: Duodenum: Polyp Adenomatous						0(50 (00())	0/50 (00/)	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
						` '		
#Intestine Small: Ileum: Adenoma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Intestine Small: Ileum: Carcinoma		0/50 (00)	0/50 (00/)			2/52 (221)	0/50 (00/)	
Overell Institutes	Tatal	0/50 (0%)	0/50 (0%)	CD 00/	Tatal	0/50 (0%)	0/50 (0%)	CD 00/
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER **Page:** 193

			Male				Female	
#Intestine Small: Ileum: Polyp Adenomatous								
•		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Intestine Small: Jejunum: Adenoma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Intestine Small: Jejunum: Carcinoma								
		2/50 (4%)	1/50 (2%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	3/100 (3%)	Mean 3%	SD 1.41%	Total	0/100 (0%)	Mean 0%	SD 0%
#Intestine Small: Jejunum: Hemangiosarcoma								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
		0/100 (0%)				` '		ט ע%
#Intestine Small: Jejunum: Leiomyosarcoma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Intestine Small: Site Unspec Adenoma	ified:							
		0/50 (0%)	1/50 (2%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	0/100 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER **Page:** 194

			Male				Female	
#Intestine Small: Site Unsp Carcinoma	ecified:							
Overall Incidence	Total	2/50 (4%) 4/100 (4%)	2/50 (4%) Mean 4%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Intestine Small: Site Unsp Carcinoma or Adenoma	ecified:		•••••					
Overall Incidence	Total	2/50 (4%) 5/100 (5%)	3/50 (6%) Mean 5%	SD 1.41%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Intestine Small: Site Unsp Hemangiosarcoma	ecified:							
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Intestine Small: Site Unsp Leiomyosarcoma								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Intestine Small: Site Unsp Polyp Adenomatous			•••••					•••••
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
*Islets, Pancreatic: Adenoma			(0.5)			(00)		
Overall Incidence	Total	1/49 (2%) 1/99 (1.01%)	0/50 (0%) Mean 1.02%	SD 1.44%	Total	0/48 (0%) 0/97 (0%)	0/49 (0%) Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

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Report Date: 06/05/2013

Route: ORAL Vehicle: WATER

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female** *Islets, Pancreatic: Carcinoma 0/49 (0%)0/50 (0%)0/48 (0%)0/49 (0%)**Overall Incidence** Total 0/99 (0%) Mean 0% SD 0% Total 0/97 (0%) Mean 0% SD 0% *Islets, Pancreatic: Carcinoma or Adenoma 1/49 (2%)0/50 (0%)0/48 (0%)0/49 (0%)**Overall Incidence** Total 1/99 (1.01%) Mean 1.02% SD 1.44% Total 0/97 (0%) Mean 0% SD 0% *Kidney: Pelvis and Transitional Epithelium: Carcinoma 0/50 (0%)0/50 (0%)0/49 (0%)0/50 (0%)**Overall Incidence** Total 0/100 (0%) Mean 0% SD 0% Total 0/99 (0%) Mean 0% SD 0% *Kidney: Pelvis and Transitional Epithelium: Carcinoma or Adenoma 0/50 (0%)0/50 (0%)0/49 (0%)0/50 (0%)**Overall Incidence** Total 0/100 (0%) Mean 0% SD 0% Total Mean 0% SD 0% 0/99 (0%) *Kidney: Renal Tubule: Adenoma 0/50 (0%)2/50 (4%)0/49 (0%)0/50 (0%)**Overall Incidence** Total 2/100 (2%) Mean 2% SD 2.83% Total 0/99 (0%) Mean 0% SD 0% *Kidney: Renal Tubule: Carcinoma 0/50 (0%)0/50 (0%)0/49 (0%)0/50 (0%)**Overall Incidence** Total Mean 0% SD 0% Mean 0% SD 0% 0/100 (0%) Total 0/99 (0%)

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER **Page:** 196

		Male Female				0/49 (0%) 0/50 (0%) Total 0/99 (0%) Mean 0% SD 0 0/49 (0%) 0/50 (0%) Total 0/99 (0%) Mean 0% SD 0 0/49 (0%) 0/50 (0%) Total 0/99 (0%) Mean 0% SD 0 Total 0/99 (0%) Mean 0% SD 0 Total 0/99 (0%) Mean 0% SD 0 0/49 (0%) 0/50 (0%) Mean 0% SD 0 0/49 (0%) 0/49 (0%) 0/49 (0%) O/49 (0%)		
*Kidney: Renal Tubule: Carcinoma or Adenoma						0/49 (0%) 0/50 (0%) al 0/99 (0%) Mean 0% 0/49 (0%) 0/50 (0%) al 0/99 (0%) Mean 0% 0/49 (0%) 0/50 (0%) al 0/99 (0%) Mean 0% 0/49 (0%) 0/50 (0%) al 0/99 (0%) Mean 0% 0/49 (0%) 0/50 (0%) al 0/99 (0%) Mean 0%		
Overall Incidence	Total	0/50 (0%) 2/100 (2%)	2/50 (4%) Mean 2%	SD 2.83%	Total	` ,	()	SD 0%
*Kidney: Renal Tubule: Hemangioma								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	` ,	` '	SD 0%
*Kidney: Renal Tubule: Hemangiosarcoma								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	` ,	` '	SD 0%
*Kidney: Renal Tubule: Plasma Cell Tumor Malign			0/50 (0%)			0/40 /00/	0/50 (09/)	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	Mean 0%	SD 0%		` ,	` ,	SD 0%
*Kidney: Renal Tubule: Sarcoma								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	` '	` ,	SD 0%
*Liver: Hemangioma								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/98 (0%)	0/49 (0%) Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: MICE
Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER **Page:** 197

			Male			1/49 (2%) 0/49 (0%) 1/98 (1.02%) Mean 1.02% SD 1.44% 38/49 (78%) 33/49 (67%) 71/98 (72.45%) Mean 72.45% SD 7.22% 11/49 (22%) 9/49 (18%) 20/98 (20.41%) Mean 20.41% SD 2.89% 12/49 (24%) 9/49 (18%) 21/98 (21.43%) Mean 21.43% SD 4.33% 40/49 (82%) 36/49 (73%)		
*Liver: Hemangiosarcoma							(4%) 2/49 (4%) 4.08%) Mean 4.08% SD 0% (2%) 0/49 (0%) 1.02%) Mean 1.02% SD 1.44% (78%) 33/49 (67%) 72.45%) Mean 72.45% SD 7.22% (22%) 9/49 (18%) 20.41%) Mean 20.41% SD 2.89% (24%) 9/49 (18%) 21.43%) Mean 21.43% SD 4.33%	
		5/50 (10%)	1/50 (2%)			2/49 (4%)	2/49 (4%)	
Overall Incidence	Total	6/100 (6%)	Mean 6%	SD 5.66%	Total	4/98 (4.08%)	Mean 4.08%	SD 0%
*Liver: Hepatoblastoma								
		6/50 (12%)	4/50 (8%)			` ,	0/49 (0%)	
Overall Incidence	Total	10/100 (10%)	Mean 10%	SD 2.83%	Total	1/98 (1.02%)	Mean 1.02%	SD 1.44%
*Liver: Hepatocellular Adenoma								
		33/50 (66%)	39/50 (78%)	00 0 1001		` ,	, ,	05
Overall Incidence	Total	72/100 (72%)	Mean 72%	SD 8.49%	Total	71/98 (72.45%)	Mean 72.45%	SD 7.22%
*Liver: Hepatocellular Carcinoma								
		26/50 (52%)	12/50 (24%)			` ,	` '	
Overall Incidence	Total	38/100 (38%)	Mean 38%	SD 19.8%	Total	, ,		SD 2.89%
*Liver: Hepatocellular Carcinoma o								
-	-	26/50 (52%)	15/50 (30%)			12/49 (24%)	9/49 (18%)	
Overall Incidence	Total	41/100 (41%)	Mean 41%	SD 15.56%	Total	21/98 (21.43%)	Mean 21.43%	SD 4.33%
*Liver: Hepatocellular Carcinoma o	or Hepatoce		40/50 (0.45)			40/40 (000/)	00/40 (700/)	
Occupation and desired	T-1-1	45/50 (90%)	42/50 (84%)	OD 4.040/	T-1-1	` '	` '	00 5 770/
Overall Incidence	Total	87/100 (87%)	Mean 87%	SD 4.24%	Total	,		

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: MICE

Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER **Page**: 198

			Male				Female	
*Liver: Hepatocellular Carcinoma	a, Hepatocellu	•				40/40 (828/)	26/40 (729/)	
Overall Incidence	Total	45/50 (90%) 87/100 (87%)	42/50 (84%) Mean 87%	SD 4.24%	Total	40/49 (82%) 76/98 (77.55%)	36/49 (73%) Mean 77.55%	SD 5.77%
*Liver: Hepatocholangiocarcinor	na	0(50 (40))	0/50 (00/)			0/40 (00/)	0/40 (00/)	
Overall Incidence	Total	2/50 (4%) 2/100 (2%)	0/50 (0%) Mean 2%	SD 2.83%	Total	0/49 (0%) 0/98 (0%)	0/49 (0%) Mean 0%	SD 0%
*Liver: Hepatocholangioma								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/49 (0%) 0/98 (0%)	0/49 (0%) Mean 0%	SD 0%
*Liver: Ito Cell Tumor Benign		0/50 (/0//)				0/40 (00/)	0/40 (00/)	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/49 (0%) 0/98 (0%)	0/49 (0%) Mean 0%	SD 0%
*Liver: Mast Cell Tumor Maligna								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/49 (0%) 0/98 (0%)	0/49 (0%) Mean 0%	SD 0%
*Liver: Plasma Cell Tumor Malig	nant							
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/49 (0%) 0/98 (0%)	0/49 (0%) Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER **Page:** 199

			Male				Female	
*Liver: Sarcoma							0/49 (0%) Mean 0%	
		0/50 (0%)	0/50 (0%)			0/49 (0%)	(/	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/98 (0%)	Mean 0%	SD 0%
*Lung: Alveolar/Bronchiolar Ac	lenoma							
		6/50 (12%)	13/50 (26%)			5/50 (10%)	` ,	
Overall Incidence	Total	19/100 (19%)	Mean 19%	SD 9.9%	Total	8/100 (8%)	Mean 8%	SD 2.83%
*Lung: Alveolar/Bronchiolar Ca	arcinoma	9/50 (18%)	7/50 (14%)			7/50 (14%)	2/50 (49/)	
Overall Incidence	Total	16/100 (16%)	Mean 16%	SD 2.83%	Total	9/100 (9%)	` ,	SD 7.07%
*Lung: Alveolar/Bronchiolar Ca		reolar/Bronchiolar Adenor 14/50 (28%)				11/50 (22%)	5/50 (10%)	
Overall Incidence	Total	33/100 (33%)	Mean 33%	SD 7.07%	Total	16/100 (16%)	` ,	SD 8.49%
*Lung: Hemangiosarcoma								
		2/50 (4%)	0/50 (0%)			0/50 (0%)	` ,	
Overall Incidence	Total	2/100 (2%)	Mean 2%	SD 2.83%	Total	0/100 (0%)	Mean 0%	SD 0%
*Lung: Plasma Cell Tumor Mali	gnant							
		0/50 (0%)	0/50 (0%)			0/50 (0%)	` '	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

#Lymph Node:

Overall Incidence

Overall Incidence

Overall Incidence

Overall Incidence

Overall Incidence

Overall Incidence

#Lymph Node, Mediastinal: Mast Cell Tumor Malignant

#Lymph Node, Mandibular: Hemangiosarcoma

#Lymph Node, Mandibular: Mast Cell Tumor Malignant

#Lymph Node, Mandibular: Plasma Cell Tumor Malignant

#Lymph Node, Bronchial: Hemangiosarcoma

Length of Study: CHRONIC

Plasma Cell Tumor Malignant

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER

Male **Female** 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/100 (0%) Mean 0% SD 0% Total 0/100 (0%) Mean 0% SD 0% 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/100 (0%) Mean 0% SD 0% Total 0/100 (0%) Mean 0% SD 0% 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/100 (0%) Mean 0% SD 0% Total 0/100 (0%) Mean 0% SD 0% 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/100 (0%) Mean 0% SD 0% Total 0/100 (0%) Mean 0% SD 0% 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/100 (0%) Mean 0% SD 0% Total 0/100 (0%) Mean 0% SD 0%

Total

0/50

0/100 (0%)

(0%)

0/50

(0%)

SD 0%

Mean 0%

Page: 200

Report Date: 06/05/2013

Total

Total

Total

Total

Total

Total

0/50

0/100 (0%)

(0%)

0/50

Mean 0%

(0%)

SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Contract/Lab: All Laboratories Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER

Length of Study: CHRONIC

Page: 201

			Male				Female	
#Lymph Node, Mesenteric: Hemangiosarcoma								
		0/50 (0%)	0/50 (0%)	05 00/		0/50 (0%)	0/50 (0%)	05 00/
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Lymph Node, Mesenteric: Plasma Cell Tumor Malignan	t							
Overell Institutes	Tatal	0/50 (0%)	0/50 (0%)	CD 00/	Tatal	0/50 (0%)	0/50 (0%)	CD 00/
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Mammary Gland: Adenoma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Mammary Gland: Carcinoma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	1/50 (2%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	1/100 (1%)	Mean 1%	SD 1.41%
#Mammary Gland: Carcinoma or Adenoma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	1/50 (2%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	1/100 (1%)	Mean 1%	SD 1.41%
#Mammary Gland: Fibroadenoma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER Page: 202

			Male				Female	
#Mammary Gland: Fibroma, Fibroadenoma	a or Adenoma							
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Mammary Gland: Fibroma, Fibroadenoma	a, Carcinoma, or	Adenoma						
		0/50 (0%)	0/50 (0%)			0/50 (0%)	1/50 (2%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	1/100 (1%)	Mean 1%	SD 1.41%
#Mesentery: Hemangioma		-/					- / / / / / / / / / /	
O	T-1-1	0/50 (0%)	0/50 (0%)	OD 00/	T-1-1	0/50 (0%)	0/50 (0%)	00, 00/
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Mesentery: Hemangiosarcoma								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 1/100 (1%)	1/50 (2%) Mean 1%	SD 1.41%
	10tai	0/100 (0%)			10tai	1/100 (1%)		SD 1.41%
#Mesentery: Lipoma								
		0/50 (0%)	1/50 (2%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	0/100 (0%)	Mean 0%	SD 0%
#Mesentery: Sarcoma								
		0/50 (0%)	0/50 (0%)	25 22/		0/50 (0%)	0/50 (0%)	00.00
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Contract/Lab: All Laboratories Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER

Length of Study: CHRONIC

Report Date: 06/05/2013

Page: 203

			Male				Female	
*Nose: Adenoma								
O !! !	T -1-1	0/50 (0%)	0/50 (0%)	OD 00/	Tatal	0/49 (0%)	0/50 (0%)	00.00/
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/99 (0%)	Mean 0%	SD 0%
*Nose: Hemangiosarcoma								
		1/50 (2%)	0/50 (0%)			0/49 (0%)	0/50 (0%)	
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	0/99 (0%)	Mean 0%	SD 0%
#Oral Cavity (Oral Mucos Papilloma Squamous o	a, Tongue, Phar	ynx, Tooth, Gingiva):						
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Oral Cavity (Oral Mucos Squamous Cell Carcin	a, Tongue, Phar							
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Oral Cavity (Oral Mucos Squamous Cell Carcin		ynx, Tooth, Gingiva): Squamous, or Papilloma 0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Oral Mucosa: Squamous Cell Carcin	oma	0/50 (001)	0/50 (05)			0/50 (00)	0(50 (00))	
	-	0/50 (0%)	0/50 (0%)	OD 00/	-	0/50 (0%)	0/50 (0%)	OD 00/
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Page: 204

Report Date: 06/05/2013

Route: ORAL Vehicle: WATER

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female** *Ovary: Choriocarcinoma 0/49 (0%)0/50 (0%)**Overall Incidence** Total 0/99 (0%) Mean 0% SD 0% *Ovary: Cystadenocarcinoma 0/49 (0%)0/50 (0%)**Overall Incidence** Total 0/99 (0%) Mean 0% SD 0% *Ovary: Cystadenoma 3/49 (6%)1/50 (2%)**Overall Incidence** Total 4/99 (4.04%) Mean 4.06% SD 2.92% *Ovary: **Granulosa Cell Tumor Benign** 0/49 (0%)0/50 (0%)**Overall Incidence** Total 0/99 (0%) Mean 0% SD 0% *Ovary: Granulosa Cell Tumor: Benign, Malignant, NOS 0/49 (0%)0/50 (0%)**Overall Incidence** Total 0/99 (0%) Mean 0% SD 0% *Ovary: Hemangioma 0/49 (0%)0/50 (0%)**Overall Incidence** Total Mean 0% SD 0% 0/99 (0%)

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Page: 205

Mean 0%

SD 0%

Report Date: 06/05/2013

Contract/Lab: All Laboratories Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER

Length of Study: CHRONIC

Male **Female** *Ovary: Hemangiosarcoma 0/49 (0%)0/50 (0%)**Overall Incidence** Total 0/99 (0%) Mean 0% SD 0% *Ovary: Luteoma 0/49 (0%)0/50 (0%)**Overall Incidence** Total 0/99 (0%) Mean 0% SD 0% *Ovary: **Plasma Cell Tumor Malignant** 0/49 (0%)0/50 (0%)**Overall Incidence** Total 0/99 (0%) Mean 0% SD 0% *Ovary: Sarcoma 0/49 (0%)0/50 (0%)**Overall Incidence** SD 0% Total 0/99 (0%) Mean 0% *Ovary: Teratoma Benign 0/49 (0%)0/50 (0%)**Overall Incidence** Total 0/99 (0%) Mean 0% SD 0% **Teratoma Malignant** 0/49 (0%)0/50 (0%)

Total

0/99 (0%)

Overall Incidence

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Page: 206

			Male				Female	
*Ovary: Tubulostromal Adenom	na					0/40 (00%)	0/50 (00/)	
Overall Incidence					Total	0/49 (0%) 0/99 (0%)	0/50 (0%) Mean 0%	SD 0%
*Ovary: Yolk Sac Carcinoma								
Overall Incidence					Total	0/49 (0%) 0/99 (0%)	0/50 (0%) Mean 0%	SD 0%
*Pancreas: Carcinoma		0/40 (00/)	0/50 (00/)			0/40 (00)	0/40 /00/	
Overall Incidence	Total	0/49 (0%) 0/99 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/48 (0%) 0/97 (0%)	0/49 (0%) Mean 0%	SD 0%
*Pancreas: Carcinoma or Adenoma	a	0/40 (00/)	0/50 (09/)			0/40 (00/)	0/40 //00/)	
Overall Incidence	Total	0/49 (0%) 0/99 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/48 (0%) 0/97 (0%)	0/49 (0%) Mean 0%	SD 0%
*Pituitary Gland: Pars Dis Adenoma		ied Site:						
Overall Incidence	Total	0/47 (0%) 0/97 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	4/50 (8%) 6/99 (6.06%)	2/49 (4%) Mean 6.04%	SD 2.77%
*Pituitary Gland: Pars Dis		ied Site:						
Overall Incidence	Total	0/47 (0%) 0/97 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/99 (0%)	0/49 (0%) Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

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Report Date: 06/05/2013

Route: ORAL Vehicle: WATER

			Male				Female	
*Pituitary Gland: Pars Di Carcinoma or Adenom		fied Site:						
		0/47 (0%)	0/50 (0%)			4/50 (8%)	2/49 (4%)	
Overall Incidence	Total	0/97 (0%)	Mean 0%	SD 0%	Total	6/99 (6.06%)	Mean 6.04%	SD 2.77%
*Pituitary Gland: Pars Int Adenoma								
		0/47 (0%)	0/50 (0%)			0/50 (0%)	0/49 (0%)	
Overall Incidence	Total	0/97 (0%)	Mean 0%	SD 0%	Total	0/99 (0%)	Mean 0%	SD 0%
*Pituitary Gland: Pars Int Carcinoma or Adenom	termedia:	0/47 (0%)	0/50 (0%)			0/50 (0%)	0/49 (0%)	
Overall Incidence	Total	0/97 (0%)	Mean 0%	SD 0%	Total	0/99 (0%)	Mean 0%	SD 0%
Salivary Glands: Adenoma		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/48 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/98 (0%)	Mean 0%	SD 0%
*Salivary Glands: Carcinoma or Adenom								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/48 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/98 (0%)	Mean 0%	SD 0%
*Salivary Glands: Hemangiosarcoma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/48 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/98 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: MICE
Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER Page: 208

Mean 0%

SD 0%

Report Date: 06/05/2013

			Male				Female	
*Salivary Glands: Mast Cell Tumor Malignant								
Overall Incidence	Total	0/50 (0%)	0/50 (0%)	SD 0%	Total	0/50 (0%)	0/48 (0%) Mean 0%	CD 00/
	Total	0/100 (0%)	Mean 0%		Total	0/98 (0%)		SD 0%
*Salivary Glands: Myxoma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/48 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/98 (0%)	Mean 0%	SD 0%
#Seminal Vesicle: Adenoma								
		0/50 (0%)	0/50 (0%)					
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%				
#Skeletal Muscle: Hemangiosarcoma		0/50 (0%)	0/50 (0%)			0/50 (0%)	1/50 (2%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	1/100 (1%)	Mean 1%	SD 1.41%
#Skeletal Muscle: Rhabdomyosarcoma								
		1/50 (2%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	0/100 (0%)	Mean 0%	SD 0%
#Skeletal Muscle: Rhabdomyosarcoma or Rhab	odomyoma						•••••	
•	•	1/50 (2%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	

SD 1.41%

Mean 1%

Total

0/100 (0%)

Total

1/100 (1%)

Overall Incidence

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: MICE Strain: B6C3F1 **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

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Report Date: 06/05/2013

Route: ORAL Vehicle: WATER

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female #Skeletal Muscle:** Sarcoma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/100 (0%) Mean 0% SD 0% Total 0/100 (0%) Mean 0% SD 0% #Skin: **Basal Cell Carcinoma** 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** 0/100 (0%) Mean 0% SD 0% Total 0/100 (0%) Mean 0% SD 0% Total #Skin: Basal Cell Carcinoma or Basosquamous Tumor (malignant or NOS) 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** 0/100 (0%) Mean 0% SD 0% Total 0/100 (0%) Mean 0% SD 0% Total #Skin: Basal Cell Carcinoma, Basal Cell Adenoma, Basosquamous Tumor (benign, malignant or NOS), or Trichoepithelioma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/100 (0%) Overall Incidence Total 0/100 (0%) Mean 0% SD 0% Total Mean 0% SD 0% #Skin:

SD 0%

SD 0%

0/50

2/50

6/100 (6%)

(4%)

0/100 (0%)

Total

Total

0/50

4/50

(0%)

(8%)Mean 6%

SD 0%

SD 2.83%

Mean 0%

Basal or Sq. Cell Carcinoma, Carcinoma, Basosq. Tumor (M or B), Basal Cell Adenoma,

Fibroma, Fibrosarcoma, Sarcoma, Myxoma, Myxosarcoma, or Fibrous Histiocytoma

0/50

0/100 (0%)

2/100 (2%)

(0%)

(2%)

0/50

1/50

Mean 0%

Mean 2%

(0%)

(2%)

Adenoma, Papilloma, Sq Papilloma, Keratoacanthoma, Trichoepithelioma

Total

Total

Overall Incidence

Overall Incidence

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER

Length of Study: CHRONIC

Contract/Lab: All Laboratories

ed Control Animal Groups Report Date: 06/05/2013
ORAL

Page: 210

			Male				Female	
#Skin: Fibrosarcoma		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Skin: Fibrosarcoma, Sarcoma	ı, Myxosarcoma	, or Fibrous Histiocytoma				0(50 (40))	4/50 (00/)	
Overall Incidence	Total	1/50 (2%) 2/100 (2%)	1/50 (2%) Mean 2%	SD 0%	Total	2/50 (4%) 6/100 (6%)	4/50 (8%) Mean 6%	SD 2.83%
#Skin: Fibrous Histiocytoma		1/50 (2%)	4/50 (20/)			0/50 (0%)	2/50 (60/)	
Overall Incidence	Total	1/50 (2%) 2/100 (2%)	1/50 (2%) Mean 2%	SD 0%	Total	0/50 (0%) 3/100 (3%)	3/50 (6%) Mean 3%	SD 4.24%
#Skin: Granular Cell Tumor Be	nign	0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Skin: Hemangioma		(20)	(20)					
Overall Incidence	Total	1/50 (2%) 1/100 (1%)	0/50 (0%) Mean 1%	SD 1.41%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Skin: Hemangiosarcoma								
Overall Incidence	Total	1/50 (2%) 2/100 (2%)	1/50 (2%) Mean 2%	SD 0%	Total	2/50 (4%) 3/100 (3%)	1/50 (2%) Mean 3%	SD 1.41%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER Page: 211

			Male			Female		
#Skin: Keratoacanthoma							0/50 (0%) Mean 0%	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)		SD 0%
#Skin: Lipoma								
Overall Incidence	Total	0/50 (0%) 1/100 (1%)	1/50 (2%) Mean 1%	SD 1.41%	Total	0/50 (0%) 0/100 (0%)	Mean 0%	
#Skin: Liposarcoma								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	` ,	SD 0%
#Skin: Mast Cell Tumor Benign						4/50 (00/)	0/50 (00/)	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	1/50 (2%) 1/100 (1%)	Mean 1%	
#Skin: Mast Cell Tumor Malignant								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	` '	SD 0%
#Skin: Melanoma Benign								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

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Report Date: 06/05/2013

Route: ORAL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: WATER

			Male			Female							
#Skin: Melanoma Malignant													
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)						
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%					
#Skin: Neural Crest Tumor													
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)						
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%					
#Skin: Neurofibroma or Schwar	nnoma benign	0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)						
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%					
#Skin: Neurofibrosarcoma or S			0/50 (0%)			0/50 (0%)	3/50 (6%)						
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	3/100 (3%)	Mean 3%	SD 4.24%					
‡Skin: Neurofibrosarcoma, Neu		chwannoma (benign, ma	lignant or NOS)										
		0/50 (0%)	0/50 (0%)			0/50 (0%)	3/50 (6%)						
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	3/100 (3%)	Mean 3%	SD 4.24%					
#Skin: Osteosarcoma													
Overall Incidence	Total	0/50 (0%)	0/50 (0%)	SD 0%	Total	0/50 (0%)	0/50 (0%)	SD 0%					
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%					

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

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Report Date: 06/05/2013

Contract/Lab: All Laboratories Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER

Length of Study: CHRONIC

			Male			Female			
#Skin: Sarcoma		0/50 (00/)	0/50 (00/)			0/50 /40/\	4/50 (00()		
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	2/50 (4%) 3/100 (3%)	1/50 (2%) Mean 3%	SD 1.41%	
#Skin: Schwannoma Benign		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)		
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%	
#Skin: Schwannoma Malignant									
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 3/100 (3%)	3/50 (6%) Mean 3%	SD 4.24%	
#Skin: Squamous Cell Carcinoma or Carcinoma	Basal Cell (Carcinoma, Basosquamou	us Tumor (malignant	or NOS),					
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	
#Skin: Squamous Cell Papilloma									
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	
#Skin: Squamous Cell Papilloma o							0/50 (00/)		
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER

Length of Study: CHRONIC

Contract/Lab: All Laboratories

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			Male			Female						
#Skin: Squamous Cell Papilloma, Papilloma, Squamous Cell Carcinoma or Keratoacanthoma 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%)												
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%				
#Skin: Squamous Cell Papilloma	, Papilloma, o		0/50 (00/)			0(50 (00))	0 (50 (00))					
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%				
#Skin: Sebaceous Gland: Adenoma												
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%				
#Skin: Sebaceous Gland: Carcinoma or Adenoma		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)					
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%				
#Spinal Cord: Hemangiosarcoma												
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%				
*Spleen: Hemangioma			(00)				(00)					
Overall Incidence	Total	0/46 (0%) 0/96 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/46 (0%) 0/95 (0%)	0/49 (0%) Mean 0%	SD 0%				

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

*Spleen:

*Spleen:

*Spleen:

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Hemangiosarcoma

Overall Incidence

Overall Incidence

Overall Incidence

Overall Incidence

Overall Incidence

Mast Cell Tumor Malignant

Plasma Cell Tumor Malignant

#Stomach, Forestomach: Squamous Cell Carcinoma Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER

Male **Female** 2/50 (4%)1/46 (2%)0/49 (0%)Mean 3.09% SD 1.29% Total 1/95 (1.05%) Mean 1.09% SD 1.54% 0/50 (0%)0/46 (0%)0/49 (0%)Mean 0% SD 0% Total 0/95 (0%) Mean 0% SD 0% 0/50 (0%)0/46 (0%)0/49 (0%)Mean 0% SD 0% Total 0/95 (0%) Mean 0% SD 0%

0/50

0/100 (0%)

1/100 (1%)

Total

Total

(0%)

0/50

(0%)

Mean 0%

Mean 1%

SD 0%

SD 1.41%

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Report Date: 06/05/2013

#Stomach, Forestomach: Squamous Cell Carcinoma	or Papilloma S	Squamous						
		0/50 (0%)	0/50 (0%)	25		0/50 (0%)	1/50 (2%)	05 4 4404
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	1/100 (1%)	Mean 1%	SD 1.41%
#Stomach, Forestomach: Squamous Cell Papilloma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	1/50 (2%)	

SD 0%

SD 0%

Total

Total

Total

Total

Total

1/46

3/96 (3.12%)

0/46

0/96 (0%)

0/46

0/96 (0%)

0/50

0/100 (0%)

0/100 (0%)

(2%)

(0%)

(0%)

(0%)

0/50

Mean 0%

Mean 0%

(0%)

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER Page: 216 Report Date: 06/05/2013

			Male				Female	
#Stomach, Glandular: Adenoma								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Stomach, Glandular: Carcinoma	•••••							
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Stomach, Glandular: Carcinoma or Adenoma		0/50 (00/)	0/50 (00/)			0(50 (001)	0/50 (00)	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
*Testes: Adenoma		0/50 (0%)	4/50 (00/)					
Overall Incidence	Total	0/50 (0%) 1/100 (1%)	1/50 (2%) Mean 1%	SD 1.41%				
*Testes: Hemangioma	•••••	0/50 (0%)	0/50 (00/)					
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%				
*Thymus: Neoplasm NOS								
Overall Incidence	Total	0/41 (0%) 0/86 (0%)	0/45 (0%) Mean 0%	SD 0%	Total	0/45 (0%) 0/95 (0%)	0/50 (0%) Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER Page: 217

			Male				Female	
*Thymus: Thymoma Benign		0/44 (00/)	0/45 (00/)			0/45 (00/)	0/50 (0%)	
Overall Incidence	Total	0/41 (0%) 0/86 (0%)	0/45 (0%) Mean 0%	SD 0%	Total	0/45 (0%) 0/95 (0%)	0/50 (0%) Mean 0%	SD 0%
*Thymus: Thymoma Malignant								
Overall Incidence	Total	0/41 (0%) 0/86 (0%)	0/45 (0%) Mean 0%	SD 0%	Total	0/45 (0%) 0/95 (0%)	0/50 (0%) Mean 0%	SD 0%
*Thymus: Thymoma: Benign, Maligna	ınt, NOS	0/41 (0%)	0/45 (0%)			0/45 (0%)	0/50 (0%)	
Overall Incidence	Total	0/86 (0%)	Mean 0%	SD 0%	Total	0/95 (0%)	Mean 0%	SD 0%
*Thyroid Gland: C-Cell: Carcinoma		0/49 (0%)	0/50 (0%)			0/48 (0%)	0/49 (0%)	
Overall Incidence	Total	0/99 (0%)	Mean 0%	SD 0%	Total	0/97 (0%)	Mean 0%	SD 0%
*Thyroid Gland: C-Cell: Carcinoma or Adenoma								
Overall Incidence	Total	0/49 (0%) 0/99 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/48 (0%) 0/97 (0%)	0/49 (0%) Mean 0%	SD 0%
*Thyroid Gland: Follicular Ce Adenoma								
Overall Incidence	Total	1/49 (2%) 2/99 (2.02%)	1/50 (2%) Mean 2.02%	SD 0.03%	Total	0/48 (0%) 0/97 (0%)	0/49 (0%) Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: WATER

Page: 218

			Male				Female	
*Thyroid Gland: Follicular Ce Carcinoma	II:	0/40 (00/)	0/50 (00/)			0/40 (00/)	0/40 (00/)	
Overall Incidence	Total	0/49 (0%) 0/99 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/48 (0%) 0/97 (0%)	0/49 (0%) Mean 0%	SD 0%
*Thyroid Gland: Follicular Ce Carcinoma or Adenoma	II:	1/49 (2%)	1/50 (2%)			0/48 (0%)	0/49 (0%)	
Overall Incidence	Total	2/99 (2.02%)	Mean 2.02%	SD 0.03%	Total	0/97 (0%)	Mean 0%	SD 0%
#Tissue NOS: Fibrosarcoma		•••••						
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Tissue NOS: Hemangiosarcoma		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Tissue NOS: Plasma Cell Tumor Maligna	ant							
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Tissue NOS: Sarcoma								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER Page: 219

			Male				Female	
#Tongue: Fibroma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Tongue: Squamous Cell Carcino	na or Papillom	a Squamous						
•	•	0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Tongue: Squamous Cell Papillom	ıa	0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Tooth: Odontoma		0/50 (00/)	0/50 (00)			0/50 (00/)	0/50 (00/)	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Urethra: Hemangiosarcoma								
-		0/50 (0%)	1/50 (2%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	0/100 (0%)	Mean 0%	SD 0%
*Urinary Bladder: Hemangiosarcoma		0/45 (00/)	0/50 (00/)			0/44 (00/)	0/50 (00/)	
Overall Incidence	Total	0/45 (0%) 0/95 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/44 (0%) 0/94 (0%)	0/50 (0%) Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Report Date: 06/05/2013

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Species: MICE Strain: B6C3F1 Route: ORAL Vehicle: WATER

Length of Study: CHRONIC

			Male				Female		
*Urinary Bladder: Plasma Cell Tumor Ma	lignant								
		0/45 (0%)	0/50 (0%)			0/44 (0%)	0/50 (0%)		
Overall Incidence	Total	0/95 (0%)	Mean 0%	SD 0%	Total	0/94 (0%)	Mean 0%	SD 0%	
tUterus: Adenoma									
						1/50 (2%)	0/50 (0%)		
Overall Incidence					Total	1/100 (1%)	Mean 1%	SD 1.41%	
#Uterus: Carcinoma									
						0/50 (0%)	0/50 (0%)		
Overall Incidence					Total	0/100 (0%)	Mean 0%	SD 0%	
#Uterus: Hemangiosarcoma									
						0/50 (0%)	1/50 (2%)		
Overall Incidence					Total	1/100 (1%)	Mean 1%	SD 1.41%	
#Uterus: Leiomyoma									
•						0/50 (0%)	0/50 (0%)		
Overall Incidence					Total	0/100 (0%)	Mean 0%	SD 0%	
#Uterus: Leiomyosarcoma									
						0/50 (0%)	0/50 (0%)		
Overall Incidence					Total	0/100 (0%)	Mean 0%	SD 0%	

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

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Report Date: 06/05/2013

Route: ORAL Vehicle: WATER

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female #Uterus: Polyp Stromal** 2/50 (4%)4/50 (8%)**Overall Incidence** Total 6/100 (6%) Mean 6% SD 2.83% **#Uterus:** Sarcoma 0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/100 (0%) Mean 0% SD 0% #Uterus: Sarcoma Stromal 0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/100 (0%) Mean 0% SD 0% #Uterus: Sarcoma Stromal or Polyp Stromal 2/50 (4%)4/50 (8%) **Overall Incidence** Total 6/100 (6%) Mean 6% SD 2.83% #Vagina: Liposarcoma 0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/100 (0%) Mean 0% SD 0% #Zymbal's Gland: Carcinoma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total Mean 0% SD 0% 0/100 (0%) Mean 0% SD 0% 0/100 (0%) Total

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

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			Male				Female	
#Zymbal's Gland: Carcinoma or Adenoma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%

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